

PATENT
Docket No. 337462000600
Client Reference BM 9619/US

#12/13
CJH
11/30/99

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington, D.C. 20231, on November 12, 1999.

DJ Macedo
Donna Macedo

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Mark M. RICHTER et al.

Serial No.: 09/074,472

Filing Date: May 7, 1998

For: ASSAYS EMPLOYING
ELECTROCHEMILUMINESCENT
LABELS AND
ELECTROCHEMILUMINESCENCE
QUENCHERS

Examiner: A. Chakrabarti

Group Art Unit: 1655

AMENDMENT UNDER 37 C.F.R. §1.111

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is in response to the Office Action dated August 11, 1999 for which a response is due on November 12, 1999 (as November 11, 1999 is a Federal holiday, 37 C.F.R. 1.7). This response is submitted within the shortened statutory period for response, and no extension of time is sought.

Please amend the above-referenced application as follows:

AMENDMENTSIn the claims:

Please amend claims 1, 24, 25, 26, and 27 as follows:

Sub C 17
1.

(Once amended) A method for [detecting] qualitative or quantitative electrochemiluminescence (ECL) detection of an analyte in a sample composition comprising the steps of:

- (a) preparing an assay mixture comprising:
- said sample composition;
 - a reagent having an ECL label; and,
 - a reagent having an ECL quenching moiety, said ECL quenching moiety comprising at least one benzene moiety;
- (b) determining any difference between the ECL emissions of:
- (i) the assay mixture prepared in step (a); and,
 - (ii) an assay mixture comprising:
 - said reagent having an ECL label;
 - said reagent having an ECL quenching moiety; and,
 - a known amount of said analyte; and,
- (c) correlating any difference determined in step (b) with the amount of analyte in said sample.

24. (Once amended) (renumbered, formerly claim 25) An assay reagent for use in the method according to claim 1, said assay reagent comprising [an] the ECL quenching moiety of claim 1, said assay reagent provided in a suitable container.

- Sub C2 25. (Once amended) (renumbered, formerly claim 26) An assay reagent for use in the method according to claim 1, said assay reagent comprising [an] the ECL quenching moiety of claim 1 and an ECL label, said assay reagent provided in a suitable container.
26. (Once amended) (renumbered, formerly claim 27) An assay reagent kit for use in the method according to claim 1, said assay reagent kit comprising an assay reagent in a suitable container, said assay reagent comprising [an] the ECL quenching moiety of claim 1, and instructions for performing said method.
- B2 27. (Once amended) (renumbered, formerly claim 28) An assay reagent kit for use in the method according to claim 1, said assay reagent kit comprising an assay reagent in a suitable container, said assay reagent comprising [an] the ECL quenching moiety of claim 1 and an ECL label, and instructions for performing said method.
-

The amendment to claim 1 finds support at, *inter alia*, page 24, line 25 through page 25, line 9 (qualitative or quantitative detection); page 25, line 29 through page 26, line 1 (qualitative or quantitative detection); and page 1, line 19 (ECL used as abbreviation for electrochemiluminescence).

The amendments to claims 24-27 are formal in nature and clarify that the ECL quenching moiety used is that of claim 1.

As no new claims are presented, no additional fees are necessitated by these amendments.

REMARKS

With entry of the above amendments, claims 1-27 are pending in the application. Applicants note the renumbering of original claims 25-28 as claims 24-27 by the Examiner, and

thank the Examiner for addressing this point. Applicants respectfully request reconsideration and allowance of the pending claims in light of the remarks made herein.

Accompanying this response is a corrected Sequence Listing as requested by the Office.

Applicants note the request for resubmission of the Information Disclosure Statement due to its being misplaced at the PTO. References for the Information Disclosure Statement are being re-ordered and the replacement Information Disclosure Statement will be resubmitted shortly.

Applicants note the objection to the drawings by the Draftperson, and request that the Examiner hold this objection in abeyance until allowable subject matter is indicated, as provided by 37 C.F.R. § 1.111(b).

Rejections Under 35 U.S.C. § 112

Claims 1-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for failing to mention whether the detection of the analyte is quantitative or qualitative. As indicated in the specification at page 24, line 25 through page 25, line 9 and page 25, line 29 through page 26, line 1, the methods of the invention can be used for either qualitative or quantitative analysis. The preamble has been amended to recite qualitative or quantitative detection, which overcomes this rejection.

Claim 1 is also rejected for use of the abbreviation "ECL" without explaining it in the preamble. The preamble has also been amended to recite "electrochemiluminescence (ECL)" to defined the abbreviation, and accordingly this rejection is also overcome.

Claims 24-27 are rejected for insufficient antecedent basis for the limitation "assay reagent comprising an ECL quenching moiety," and consequent vagueness and indefiniteness.

The Examiner states that "[t]he phrase 'an ECL quenching moiety' does not point specifically to the claim 1 moiety and may be confusingly interpreted as 'any' such moiety." Claims 24-27 have been amended to clarify that the ECL quenching moiety is that of claim 1, and accordingly this rejection is overcome.

Rejections Under 35 U.S.C. § 102

Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al (U.S. Patent 4,293,310) (October 6, 1981).

This rejection is respectfully traversed. The Examiner noted that the rejection was applied due to the unclarity of the claims as summarized under the 35 U.S.C. § 112 ¶2 rejections. As indicated above, claims 24 and 25 have been amended to indicate that the ECL quenching moiety is indeed the quenching moiety of claim 1. Accordingly, the amendments to the claims overcome this grounds for rejection.

The Examiner also states that "Weber expressly teaches an ECL (electrochemiluminescence) label and the ECL quenching moiety and instructions to use them...for the electrochemiluminescence assay. In this context, it is noteworthy that 'electrochemiluminescence' and 'photoelectrochemical' are synonym[s] because the scientific principles and theories which form the basis of these assays are basically [the] same." The applicants respectfully disagree. Electrochemiluminescence refers to the process by which a chemical or chemicals are excited by an electrode, which then emit a photon upon relaxation to the ground state. See the instant specification, page 2, line 27 to page 3, line 17. In contrast, photoelectrochemistry refers to the process by which a chemical is excited by absorbing a photon, and which relaxes by ejecting an electron. See Weber, col. 3, lines 40-45, and col. 4, lines 6-10 ("A photoelectrochemically active molecule is herein defined as a molecule which when in solution produces an electrical current at an electrode in response to input of light into the solution.") Thus, electrochemiluminescence produces output light energy as a product of

electrical excitation, while photoelectrochemistry produces output electrical energy as a product of light excitation, and the two processes cannot be held to be synonymous.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Chemical Company (Catalog 1995).

This rejection is respectfully traversed. The Examiner notes that reagents such as phenol and benzenecarboxylic acids are disclosed in the prior art. Applicants, however, are not claiming chemicals such as phenol *per se* in claim 24, but rather the electrochemiluminescence reagents used for the process described in claim 1. This is clarified by the amendment to claim 24. Accordingly, Applicants respectfully traverse this rejection.

Rejections Under 35 U.S.C. § 103

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber (U.S. Patent 4,293,310) (October 6, 1981) in view of Stratagene Catalog (1988, Page 39).

This rejection is respectfully traversed. Claims 26 and 27 have been amended to indicate that the ECL quenching moiety is that of claim 1. In addition, as discussed above in the response to the rejections under 35 U.S.C. §102(b), Weber's photoelectrochemical process is quite distinct from the Applicants' electrochemiluminescence process. Electrochemiluminescence produces output light energy as a product of electrical excitation, while photoelectrochemistry produces output electrical energy as a product of light excitation. Thus Weber is not applicable as a reference against an electrochemiluminescence assay. Given the amendments to the claims, and given the deficiency of the primary reference, which is not cured by the secondary reference, Applicants respectfully traverse this rejection.

CONCLUSION

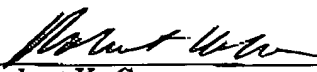
Applicants submit that all issues raised in the Office Action (Rejections Under 35 U.S.C. § 112; Rejections Under 35 U.S.C. § 102; Rejections Under 35 U.S.C. § 103; Correction of Sequence Listing; Draftperson's Objection to Drawings) are addressed by this response and its accompanying papers. The Information Disclosure Statement will be resubmitted shortly, and Applicants will endeavor to submit it in time for it to be considered prior to or with consideration of this response. Accordingly, Applicants respectfully solicit early allowance of the pending claims as amended.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 337462000600. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: November 12, 1999

By:


Robert K. Cerpa
Registration No. 39,933

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5840
Facsimile: (650) 494-0792